



Traditional 510(k) for the  
Molecular Adsorbent Recirculating System (MARS®)

DEC 14 2012

## 5.0 510(k) SUMMARY

This summary of 510(k) safety and effectiveness has been submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of Gambro's knowledge.

<b>Submitter's Name</b>	Gambro Renal Products, Inc.
<b>Address</b>	14143 Denver West Parkway, Suite 400 Lakewood, Colorado 80401
<b>Establishment Registration No.</b>	2087532
<b>Contact Person</b>	Kae Miller, Regulatory Affairs Manager, Americas
<b>Telephone Number</b>	303.222.6724
<b>Fax Number</b>	303.222.6916
<b>Date of Summary</b>	December 14, 2012
<b>Device under clearance</b>	
<b>Name of the Device</b>	Molecular Adsorbent Recirculating System (MARS®)
<b>Common or Usual Name</b>	Apparatus, Hemoerfusion, Sorbent
<b>Classification Name</b>	Sorbent Hemoperfusion System
<b>Device Class</b>	III
<b>Product Code</b>	78 FLD
<b>Regulation Number</b>	21 CFR 876.5870
<b>Predicate Device Information (1)</b>	
<b>Name of the Device</b>	BioLogic-DT® System (BioLogic-DT-1000 with DT-1000-TK)
<b>510(k) Number</b>	K984546 (cleared on August 13, 1999)
<b>Classification Name</b>	Sorbent Hemoperfusion System
<b>Device Class</b>	III
<b>Product Code</b>	78 FLD
<b>Regulation Number</b>	21 CFR 876.5870
<b>Predicate Device Information (2)</b>	
<b>Name of the Device</b>	BioLogic-DT® System (BioLogic-DT-1000 with DT-1000-TK)
<b>510(k) Number</b>	K99216 (cleared on September 10, 1999)
<b>Classification Name</b>	Sorbent Hemoperfusion System
<b>Device Class</b>	III
<b>Product Code</b>	78 FLD and FKT
<b>Regulation Number</b>	21 CFR 876.5870
<b>Predicate Device Information (3)</b>	



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<b>Name of the Device</b>	Molecular Adsorbent Recirculating System (MARS®)
<b>510(k) Number</b>	K033262 (cleared on May 27, 2005)
<b>Classification Name</b>	Sorbent Hemoperfusion System
<b>Device Class</b>	III
<b>Product Code</b>	FLD and NKL
<b>Regulation Number</b>	21 CFR 876.5870

#### **Additional Precaution:**

*Patients treated with MARS® may experience a decrease in blood platelet counts during their treatment due to loss of platelets in the extracorporeal circuit, as with other extracorporeal blood treatments involving medical devices (i.e. acute and chronic hemodialysis, membrane plasmapheresis, continuous renal replacement therapy (CRRT), etc.).*

#### **INDICATIONS FOR USE**

*The MARS® is indicated for the treatment of drug overdose and poisonings. The only requirement is that the drug or chemical be dialyzable (in unbound form) and bound by charcoal and/or ion exchange resins.*

*The MARS® is indicated in the treatment of Hepatic Encephalopathy (HE) due to a decompensation of a chronic liver disease. Clinical trials conducted with MARS® treatments in HE patients having a decompensation of chronic liver disease demonstrated a transient effect from MARS® treatments to significantly decrease their hepatic encephalopathy scores by at least 2 grades compared to standard medical therapy (SMT).*

#### **Contraindication:**

*The MARS® is not indicated as a bridge to liver transplant. Safety and efficacy has not been demonstrated for this indication in controlled, randomized clinical trials.*

*The effectiveness of the MARS® device in patients that are sedated could not be established in clinical studies and therefore cannot be predicted in sedated patients.*

#### **DEVICE DESCRIPTION**

The MARS® is a blood detoxification device comprised of dialyzers, adsorption columns, tubing connectors and a monitor unit. It is designed for the combined removal of water-soluble low and middle molecular weight substances and albumin bound molecules. The treatment is based on the dialysis of blood against an albumin-containing dialysate solution.



Traditional 510(k) for the  
Molecular Adsorbent Recirculating System (MARS®)

#### **BRIEF DISCUSSION CLINICAL PERFORMANCE DATA:**

The presented data from controlled, multi-center clinical trials support the following new indication for use for MARS® and demonstrate that the device is performing at least as safe and effective as the identified predicate devices.

The MARS® performs albumin dialysis to remove low molecular weight water-soluble solutes and albumin-bound solutes such as drugs and toxins, from the patient's blood.

See Attachment 1.

#### **SUBSTANTIAL EQUIVALENCE**

The MARS® is substantially equivalent to the predicate devices since the basic features function and technologies are the same. The minor differences raise no new issues of safety and effectiveness.



Traditional 510(k) for the  
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## 5.1 DEVICE COMPARISON TABLE

CATEGORY	DEVICE: MARS®	PREDICATE: MARS® K033262	PREDICATE: BioLogic-DT System K984546 and K992196
Indications for use	<p>The MARS® is indicated for the treatment of drug overdose and poisonings. The only requirement is that the drug or chemical be dialyzable (in unbound form) and bound by charcoal and/or ion exchange resins.</p> <p>The MARS® is indicated in the treatment of Hepatic Encephalopathy (HE) due to a decompensation of a chronic liver disease.</p> <p>Clinical trials conducted with MARS® treatments in HE patients having a decompensation of chronic liver disease demonstrated a transient effect from MARS® treatments to significantly decrease their hepatic encephalopathy scores by at least 2 grades compared to standard medical therapy (SMT).</p>	<p>The MARS® is indicated for the treatment of drug overdose and poisonings. The only requirement is that the drug or chemical be dialyzable (in unbound form) and bound by charcoal and/or ion exchange resins.</p>	<p><b>Acute Hepatic Encephalopathy:</b> The BioLogic-DT System is indicated for the treatment of acute Hepatic Encephalopathy due to decompensation of chronic liver disease or fulminant hepatic failure.</p> <p><b>Drug Overdose and Poisonings:</b> The BioLogic-DT System is indicated for the treatment of drug overdose and poisonings. The only requirement is that the drug or chemical be dialyzable (in unbound form) and bound by charcoal, such as acetaminophen, tricyclics, barbiturates, tranquilizers, anticancer agents, antimicrobials, theophylline, herbicides, and insecticides.</p>

<b>CATEGORY</b>	<b>DEVICE: MARS®</b>	<b>PREDICATE: MARS® K033262</b>	<b>PREDICATE: BioLogic-DT System K984546 and K992196</b>
<b>Contraindications</b>	<i>The MARS® is not indicated as a bridge to liver transplant. Safety and efficacy has not been demonstrated for this indication in controlled, randomized clinical trials. The effectiveness of the MARS® device in patients that are sedated could not be established in clinical studies and therefore cannot be predicted in sedated patients.</i>	The MARS® is not indicated for the treatment of chronic liver disease conditions or as a bridge to liver transplant. Safety and efficacy has not been demonstrated for these indications in controlled, randomized clinical trials.	The BioLogic DT is not indicated for the treatment of chronic liver conditions as a bridge to liver transplant.
<b>Treatment kit components</b>	2 dialyzers 2 sorbent columns Activated carbon Ion exchanger 1 tubing set consisting of tubing/connectors/clamps/hydrophobic and particle filters/heater bag/air traps	2 dialyzers 2 sorbent columns Activated carbon Ion exchanger 1 tubing set consisting of tubing/connectors/clamps/hydrophobic and particle filters/heater bag/air traps	1 dialyzer Chemical sorbents Activated charcoal (carbon) Ion exchanger (powdered) Tubing set
<b>Dialyzer type/membrane material (blood contacting)</b>	Hollow fiber dialyzer/polyamix (PAES)	Hollow fiber dialyzer/polyamix (PAES)	Plate membrane dialyzer/ Cellulose acetate
<b>Sorbents</b>	Activated Charcoal (contained in a column) Ion exchanger (contained in a column)	Activated Charcoal (contained in a column) Ion exchanger (contained in a column)	Finely powdered Activated Charcoal (in suspension) Powdered carbon exchanger (in suspension)
<b>Carrier</b>	Albumin in saline	Albumin in saline	Polyvinylpyrrolidone (PVP) and Pluronic polyols in saline

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<b>CATEGORY</b>	<b>DEVICE: MARS®</b>	<b>PREDICATE: MARS® K033262</b>	<b>PREDICATE: BioLogic-DT System K984546 and K992196</b>
<b>Blood circulation method</b>	None: hemodialysis system controls blood flow	None: hemodialysis system controls blood flow	Alternating pressure and vacuum ("push-pull" effect) to propel blood through circuit (positive pressure and vacuum pump)
<b>Sorbent/dialysate circulation method</b>	Roller pump	Roller pump	Alternating pressure and vacuum
<b>Operation modes</b>	Preparation (priming) Treatment	Preparation (priming) Treatment	Preparation (priming) Treatment
<b>User interface control (display)</b>	Select manual/automatic operation Review/change treatment parameters Monitor device status	Select manual/automatic operation Review/change treatment parameters Monitor device status	Automatic Operation only  Monitor device status
<b>Automated monitoring</b>	In-line pressure Albumin dialysate temperature Blood leak Albumin dialysate flow rate Pump door position Line voltage	In-line pressure Albumin dialysate temperature Blood leak Albumin dialysate flow rate Pump door position Line voltage	Sorbent temperature Blood leak Air bubble Blood flow rate
<b>Alarms</b>	Blood leak Pressure Temperature	Blood leak Pressure Temperature	Blood leak Air detector
<b>Blood volume in circuit</b>	200-250mL	200-250mL	200-250mL



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

December 14, 2012

Gambro Renal Products, Inc.  
% Ms. Kae Miller  
RA Manager, Americas  
14143 Denver West Parkway, Suite 400  
LAKEWOOD CO 80401

Re: K113313  
Trade/Device Name: Molecular Adsorbent Recirculating System (MARS®)  
Regulation Number: 21 CFR§ 876.5870  
Regulation Name: Sorbent hemoperfusion system  
Regulatory Class: III  
Product Code: FLD  
Dated: December 5, 2012  
Received: December 10, 2012

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Herbert R. Lerner

for

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,  
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

**Indications for Use**510(k) Number (if known): K113313

Device Name: Molecular Adsorbent Recirculating System (MARS®)

**Indications for Use Statement**

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)**Herbert P. Lerner**

(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and  
Urological Devices

510(k) Number

K113313